Boston Scientific

Advancing science for life™

WATCHMAN™ Left Atrial Appendage Closure Device

www.watchmandevice.com

SH-230609-AD JUN2015

AF is a Growing Problem Associated with Greater Morbidity and Mortality

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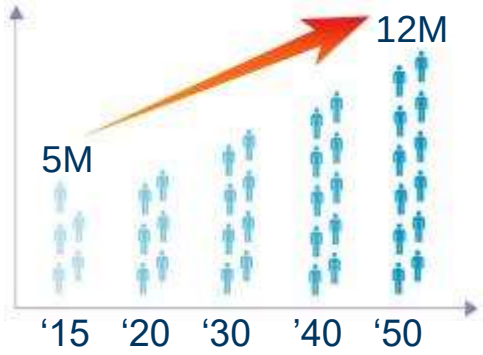
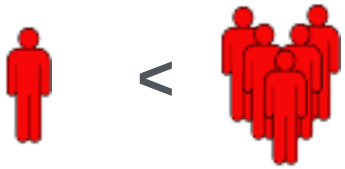
AF = most common cardiac arrhythmia, and growing



AF increases risk of stroke



~5 M
people with AF in U.S., expected to more than double by 2050[1]

5x
greater risk of stroke with AF[2]

- Higher stroke risk for older patients and those with prior stroke or TIA
- 15-20% of all strokes are AF-related
- AF results in greater disability compared to non-AF-related stroke
- High mortality and stroke recurrence rate

1. Go AS. et al, Heart Disease and Stroke Statistics—2013 Update: A Report From the American Heart Association. Circulation. 2013; 127: e6-e245.
2. Holmes DR, Atrial Fibrillation and Stroke Management: Present and Future, Seminars in Neurology 2010;30:528–536.

2014 ACC/AHA/HRS Treatment Guidelines to Prevent Thromboembolism in Patients with AF

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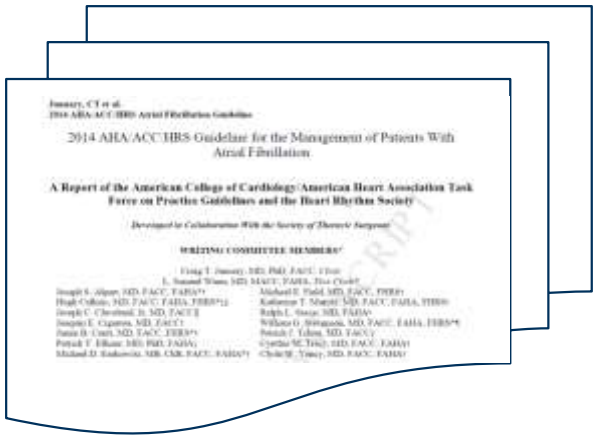
- Assess stroke risk with CHA_2DS_2-VASc score
  - Score 1: Annual stroke risk 1%, oral anticoagulants or aspirin may be considered
  - Score ≥2: Annual stroke risk 2%-15%, **oral anticoagulants are recommended**
- Balance benefit vs. bleeding risk



2014 AHA/ACC/HRS Guideline for the Management of Patients with AF

January, CT. et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation. JACC. 2014; doi: 10.1016/j.jacc.2014.03.022

Oral Anticoagulation is Standard of Care, but Not Ideal for All

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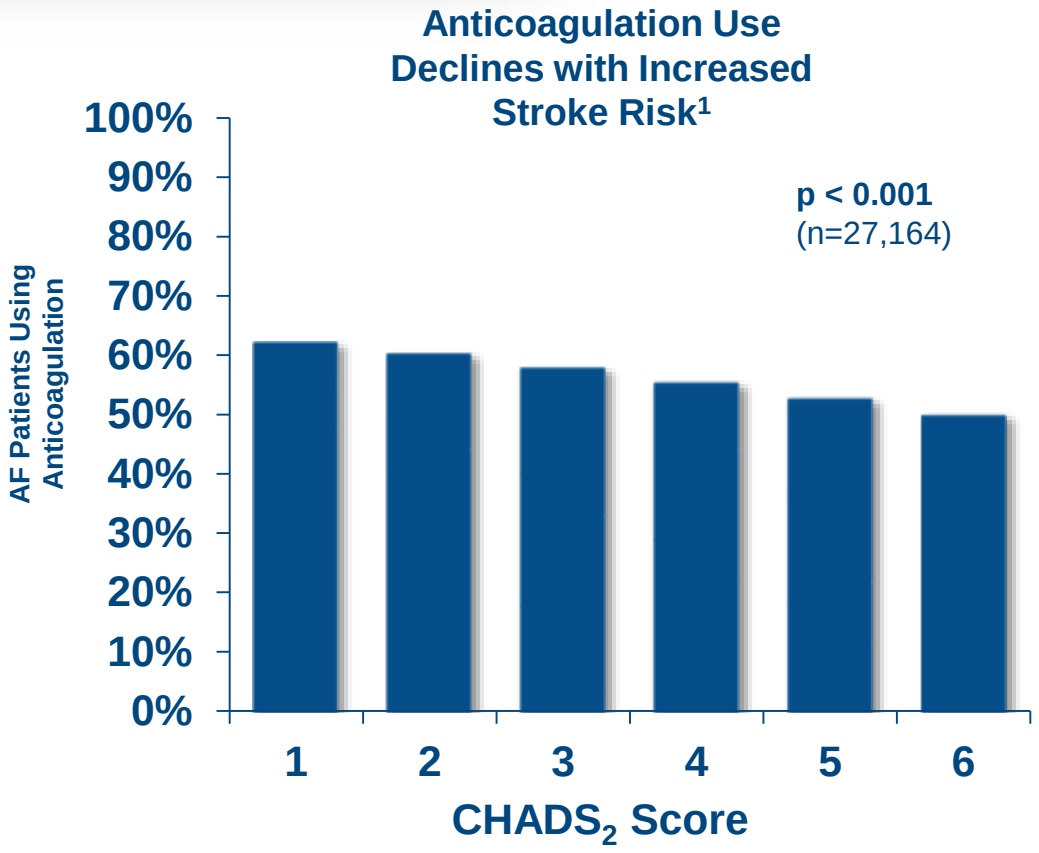
Warfarin

- Bleeding risk
- Daily regimen
- High non-adherence rates
- Regular INR monitoring
- Food and drug interaction issues
- Complicates surgical procedures

Novel Oral Anticoagulants

- Bleeding risk
- Daily regimen
- High non-adherence rates
- Complicates surgical procedures
- Lack of reversal agents
- High cost



1. Piccini, et al.. Pharmacotherapy in Medicare beneficiaries with atrial fibrillation. Heart Rhythm. 2012;9:1403-1408

Despite Increasing NOAC Adoption, Overall Rate of Anticoagulation in High Risk NVAF Patients has Not Improved

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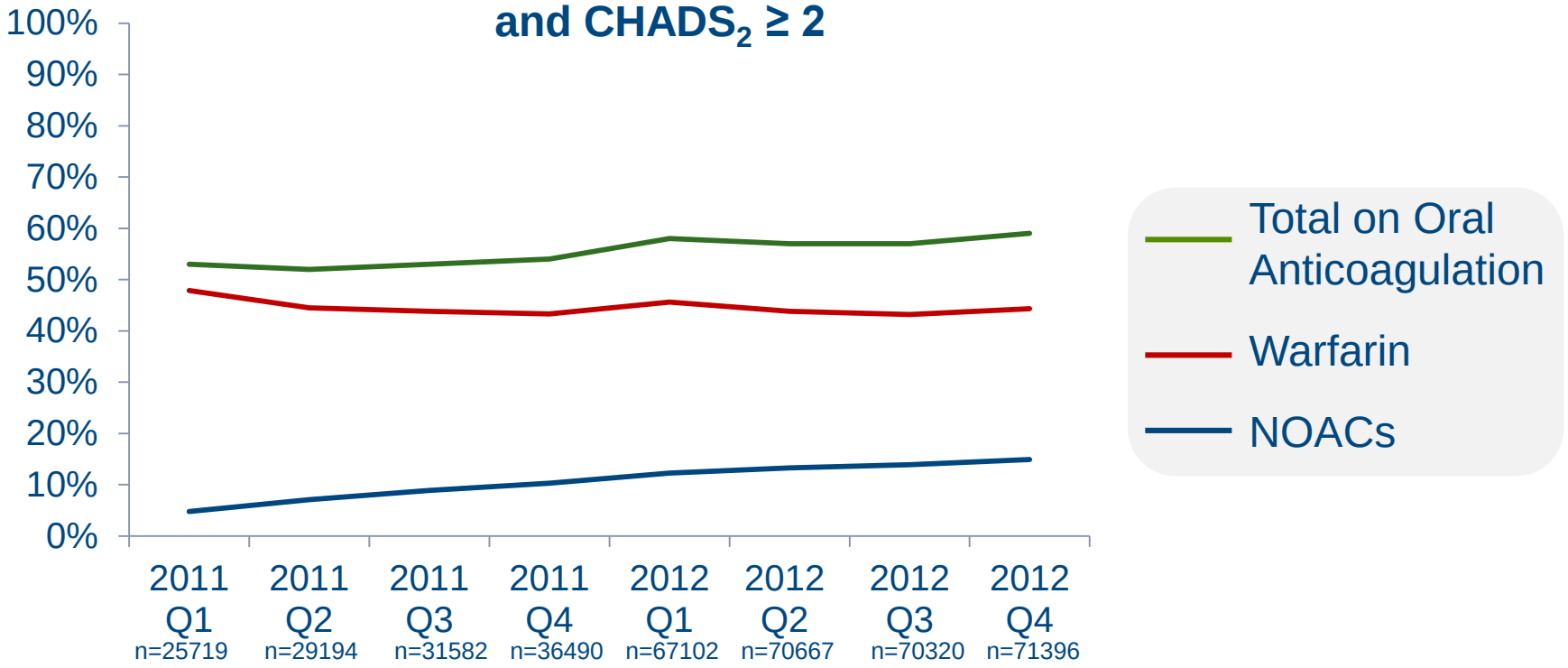
Anticoagulant Use in Patients with NVAF and $CHADS_2 \geq 2$



Results from the NCDR PINNACLE Registry[1]

1. Jani, et al. Uptake of Novel Oral Anticoagulants in Patients with Non-Valvular and Valvular Atrial Fibrillation: Results from the NCDR-Pinnacle Registry. ACC 2014

Introducing the WATCHMAN™ LAAC Device

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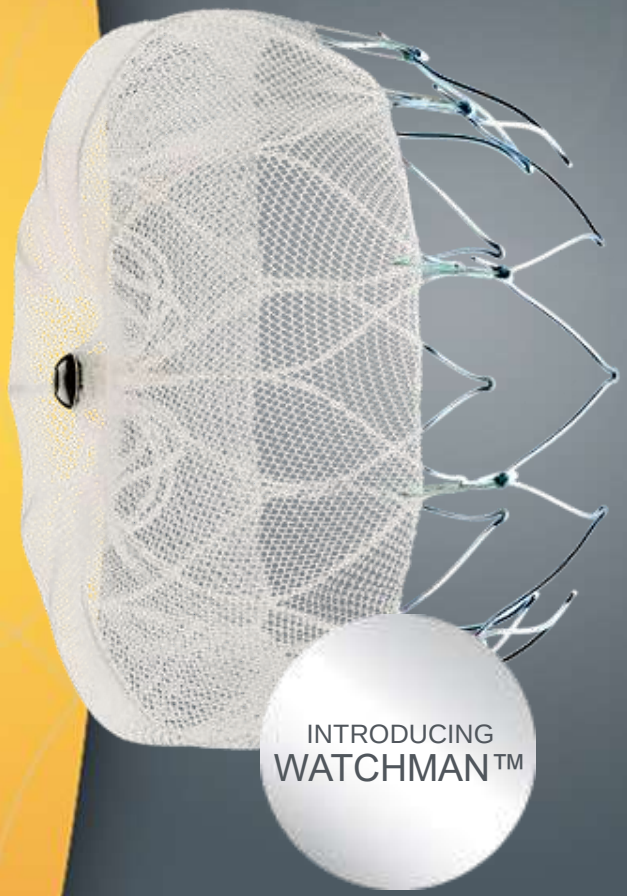
A **first-of-its-kind, proven alternative** to long-term warfarin therapy for stroke risk reduction in patients with non-valvular AF

Most studied LAAC therapy, only one proven with long-term data from randomized trials or multi-center registries

Comparable stroke risk reduction, **and statistically superior reductions in hemorrhagic stroke, disabling stroke and cardiovascular death** compared to warfarin over long-term follow-up[1,2]



1. Reddy, V et al. JAMA 2014; Vol. 312, No. 19.
2. Reddy, V et al. Watchman I: First Report of the 5-Year PROTECT-AF and Extended PREVAIL Results. TCT 2014.

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WATCHMAN Therapy

Indications for Use

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The WATCHMAN™ Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for warfarin; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

WATCHMAN™ LAAC Closure Device

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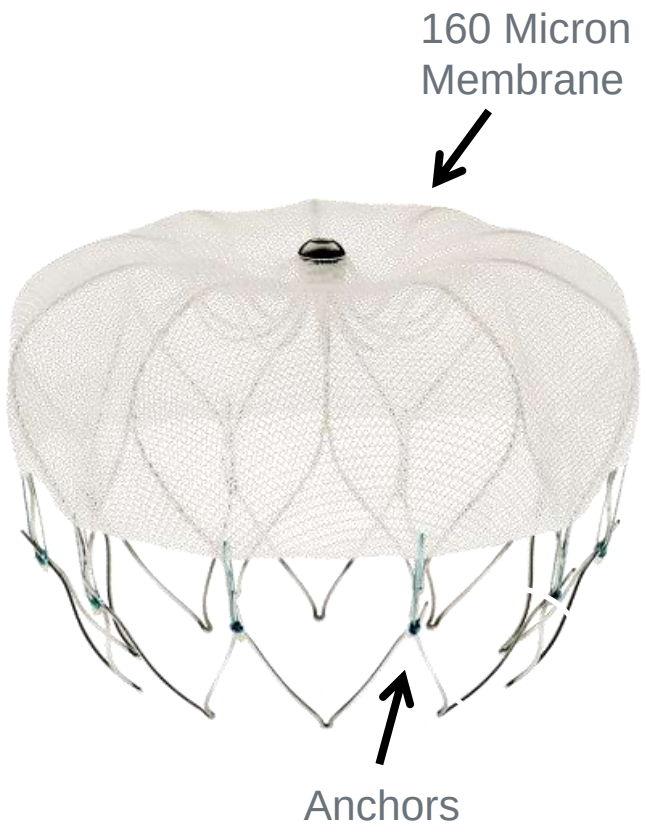

Minimally Invasive, Local Solution

- Available sizes: 21, 24, 27, 30, 33 mm diameter

Intra-LAA design

- Avoids contact with left atrial wall to help prevent complications

Nitinol Frame

- Conforms to unique anatomy of the LAA to reduce embolization risk
- 10 active fixation anchors - designed to engage tissue for stability

Proximal Face

- Minimizes surface area facing the left atrium to reduce post-implant thrombus formation
- 160 micron membrane PET cap designed to block emboli and promote healing

Warfarin Cessation

- 92% after 45 days, >99% after 12 months[1]
- 95% implant success rate[1]

1. Holmes, DR et al. JACC 2014; Vol. 64, No. 1

WATCHMAN™ Pre-Loaded Delivery System

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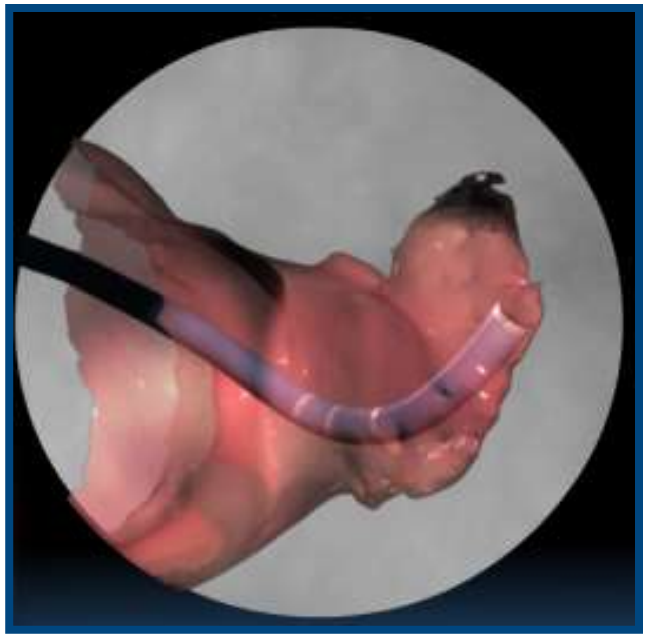
WATCHMAN™ Access Sheath

14F outer diameter (4.7mm), 12F inner diameter (4mm)
75 cm working length



Preformed access sheath curve shapes guide position in LAA

WATCHMAN™ Delivery Sheath

WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device Procedure

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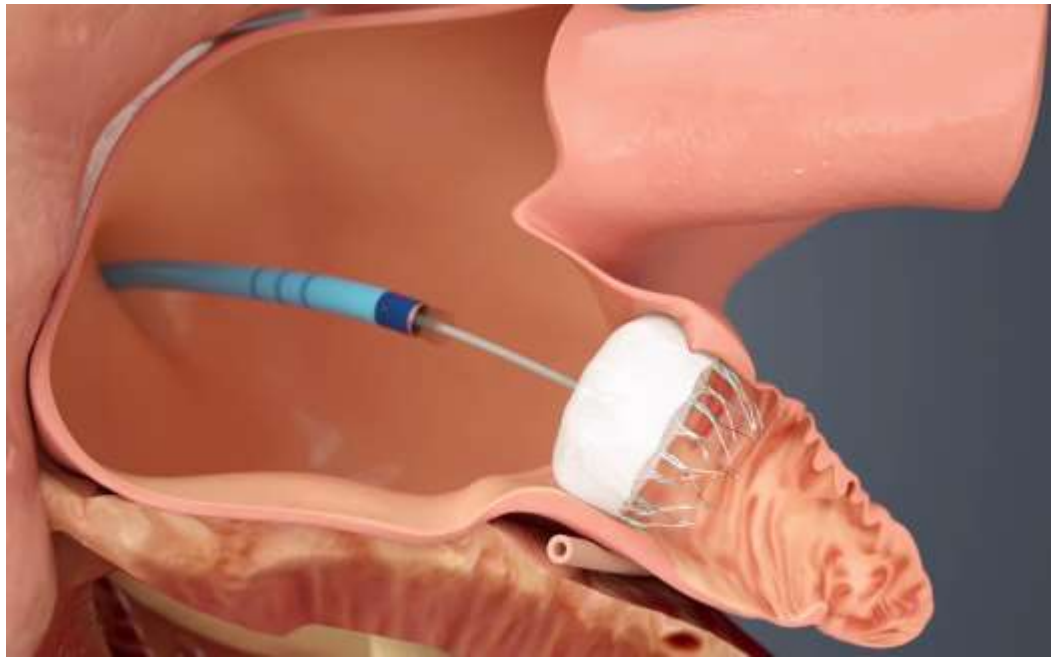
- One-time implant that does not need to be replaced
- Performed in a cardiac cath lab/EP suite, does not need hybrid OR
- Performed by a Heart Team
  - IC/EP or IC&EP, TEE, General Anesthesia, Surgical Back- up, WATCHMAN Clinical Specialist
- Transfemoral Access: Catheter advanced to the LAA via the femoral vein
  (Does not require open heart surgery)
- General anesthesia*
- 1 hour procedure*
- 1-2 day hospital stay*



* Typical to patient treatment in U.S. clinical trials

WATCHMAN™ LAAC Procedure

Implant Video

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Device Release Criteria: PASS

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WATCHMAN™ Device features one-step deployment
Recapturable and Repositionable

All criteria must be met prior to device release (PASS)

Position – device is distal to or at the ostium of the LAA

Anchor – fixation anchors engaged / device is stable

Size – device is compressed 8-20% of original size

Seal – device spans ostium, all lobes of LAA are covered

Device Release Criteria – Position

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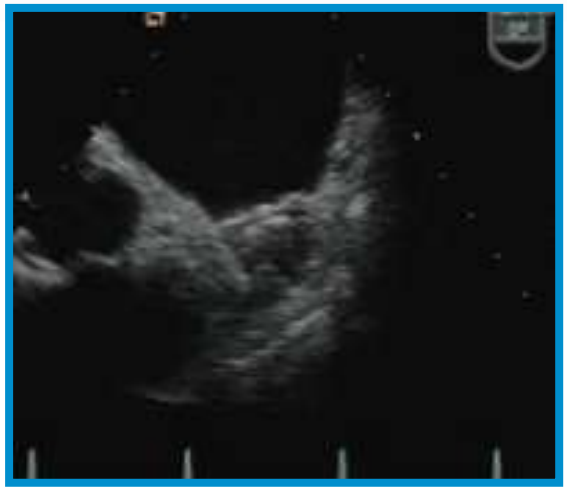
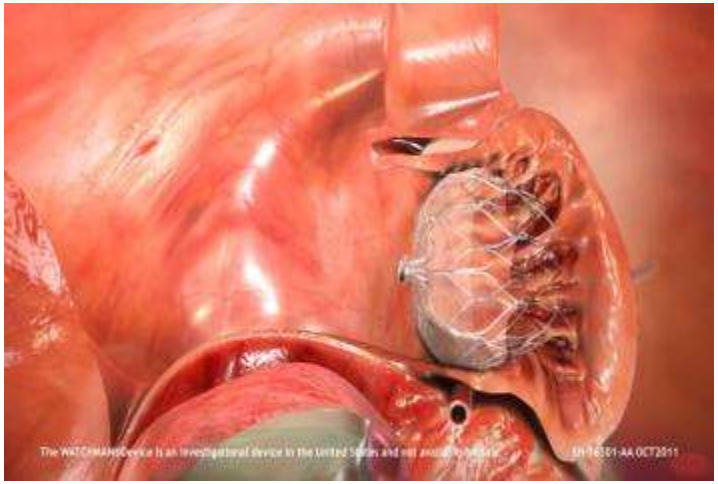
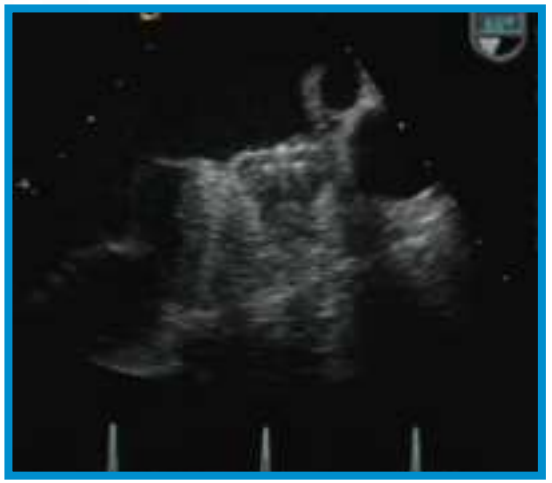
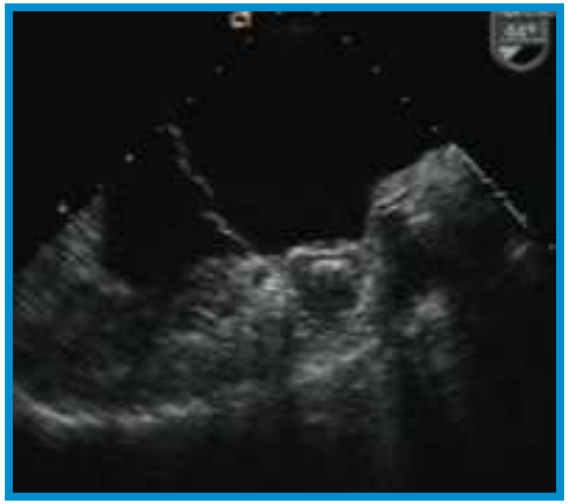
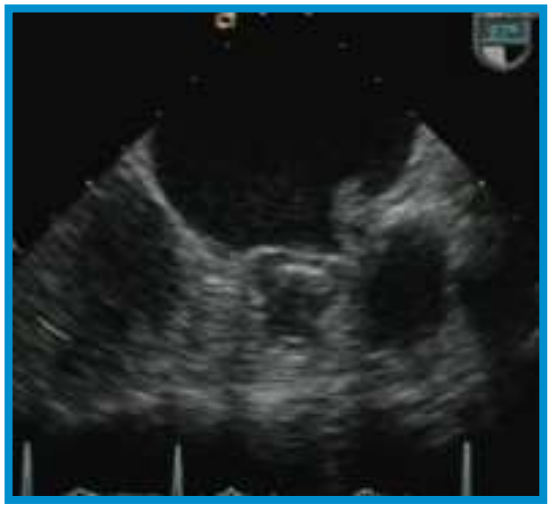
Device should be at or just distal to the LAA ostium

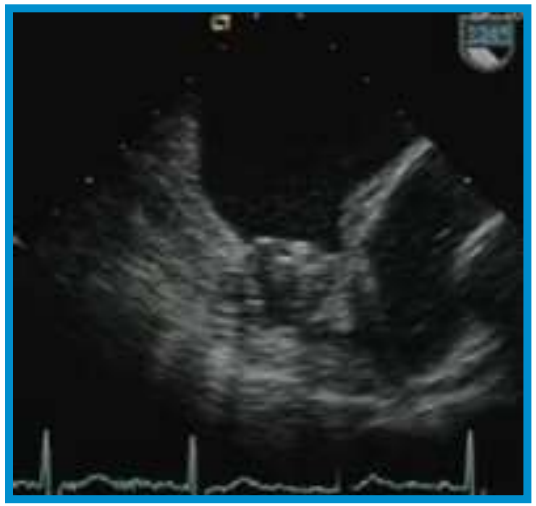












Device Release Criteria – Anchor

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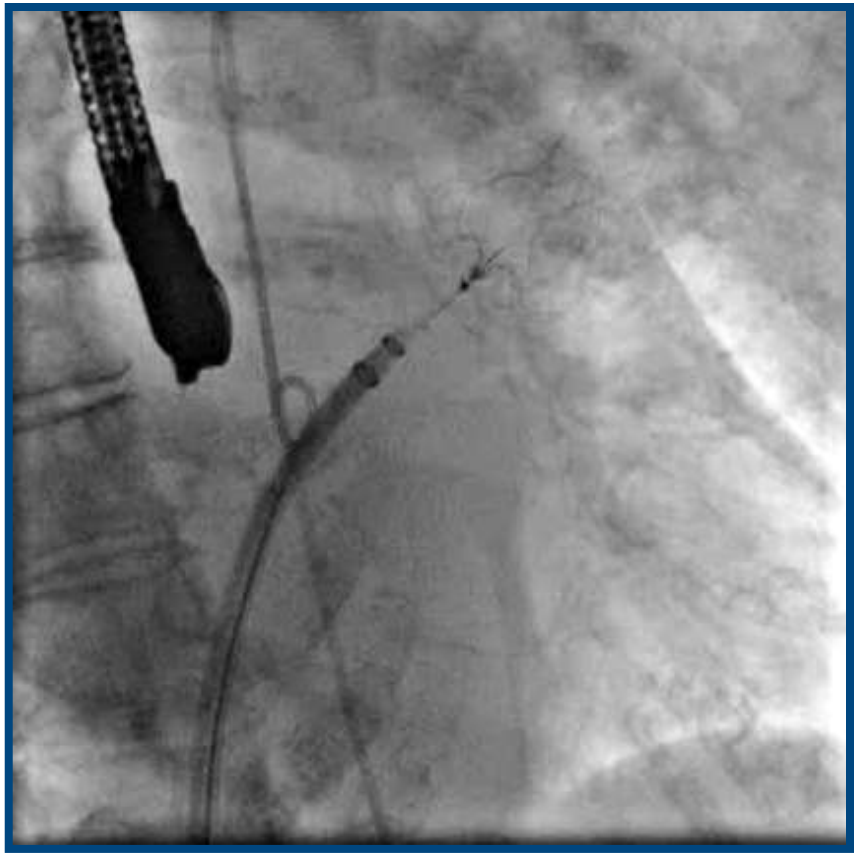
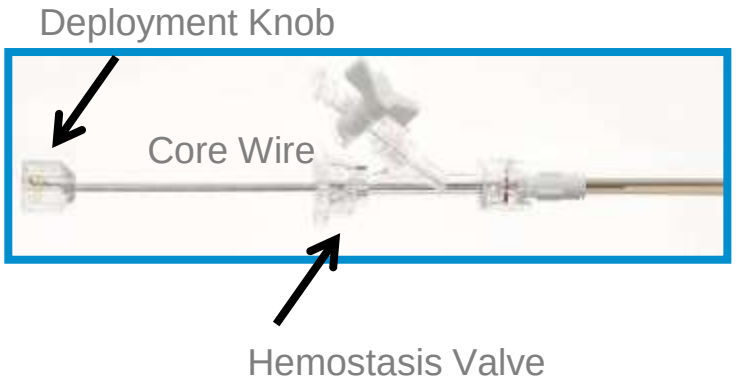
Pass or Fail Test



1. To test stability, gently retract deployment knob and let go, observe device returns to original position



2. If the device moves to where position is no longer acceptable or the compression is no longer sufficient, the device should be recaptured
3. Test stability more than once if device stability is questionable

Device Release Criteria - Size

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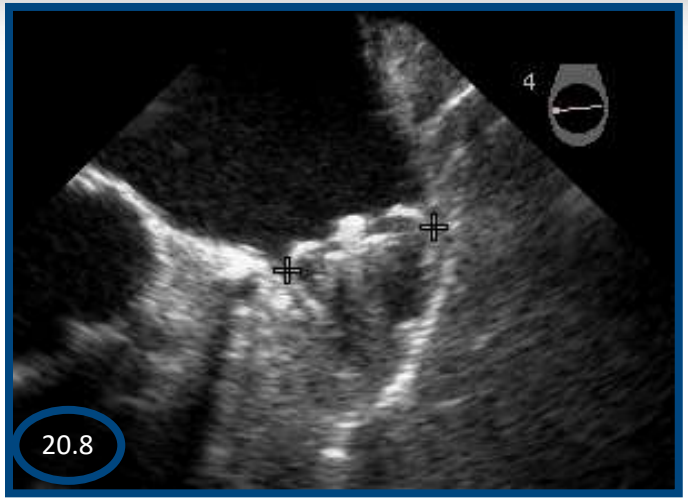

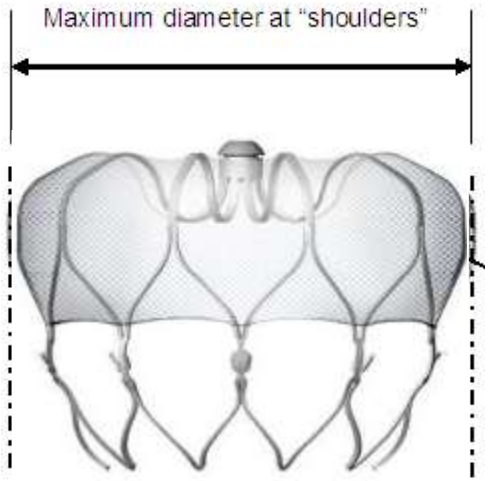

"threaded insert" must be visible when measuring on echo to ensure device was measured at widest cross-section in all angles

Device Compression Table

8 – 20% of original device size selected

Device Size *(uncompressed diameter)*	**Maximum (20%)** Compression Measured Diameter*	**Minimum (8%)** Compression Measured Diameter*
21	16.8 mm	19.3 mm
24	19.2 mm	22.1 mm
27	21.6 mm	24.8 mm
30	24.0 mm	27.6 mm
33	26.4 mm	30.4 mm

**Measure in-situ device diameter at approximate TEE angles of 0, 45, 90 and 135 degrees to accurately assess device compression*

Device Release Criteria – Seal

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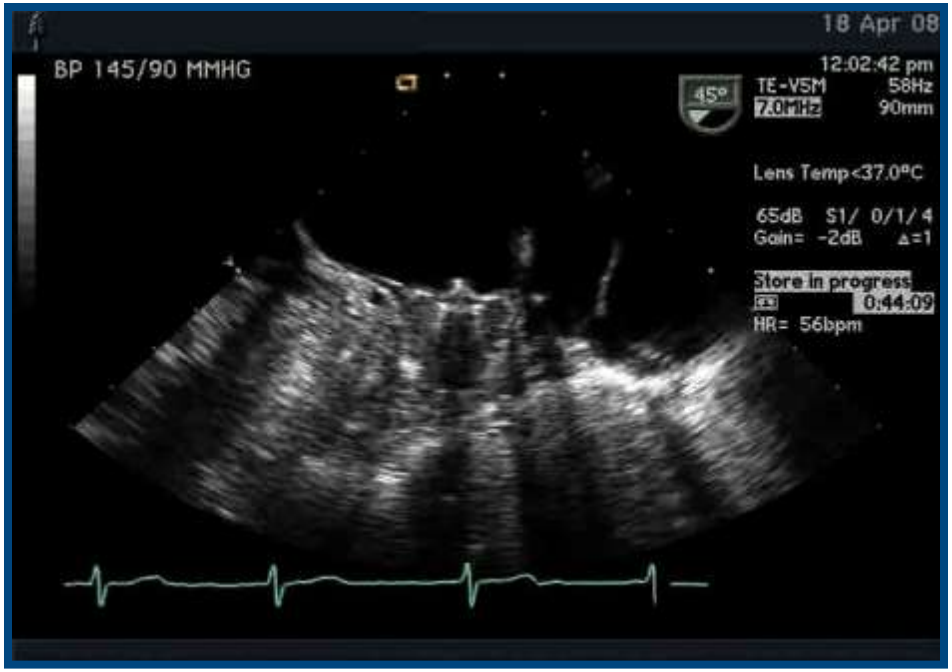
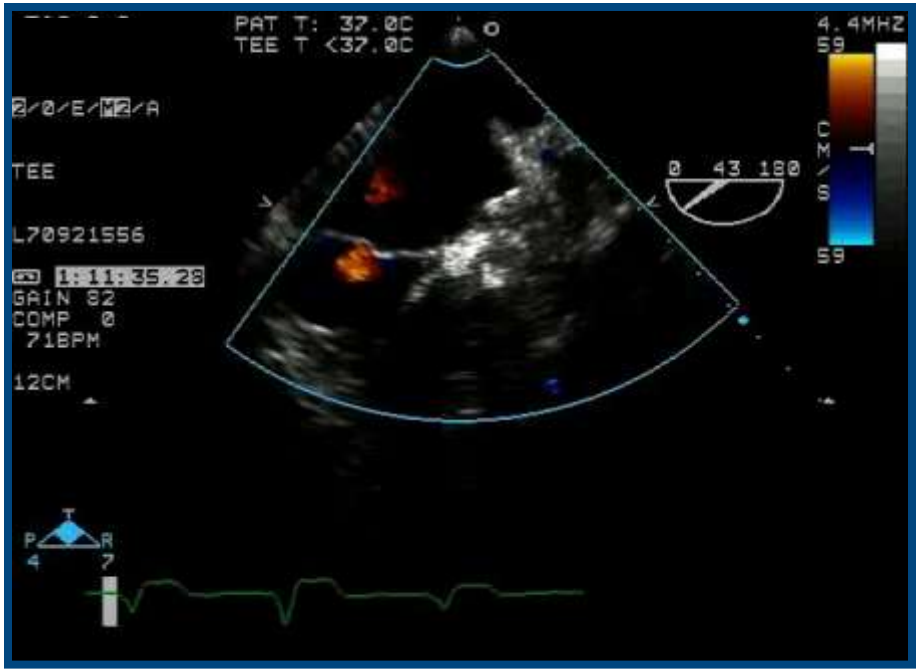
Residual flow around the device of ≤ 5mm acceptable





- If all 4 device release criteria are met (PASS), device can be released
- Counter clockwise on proximal handle 3-5 turns

WATCHMAN™ Device Endothelialization

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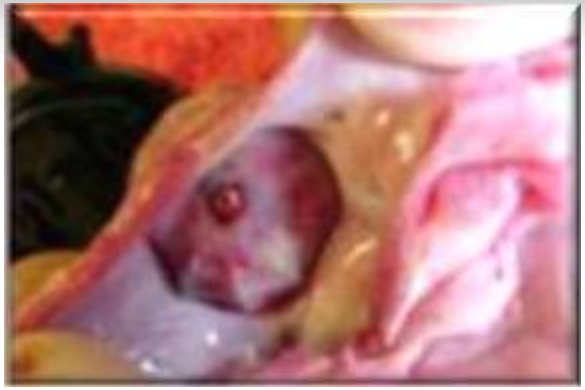
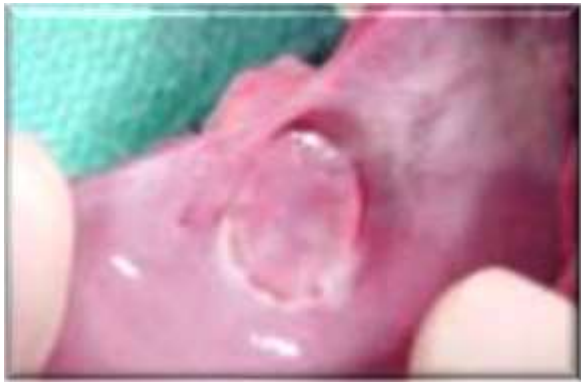
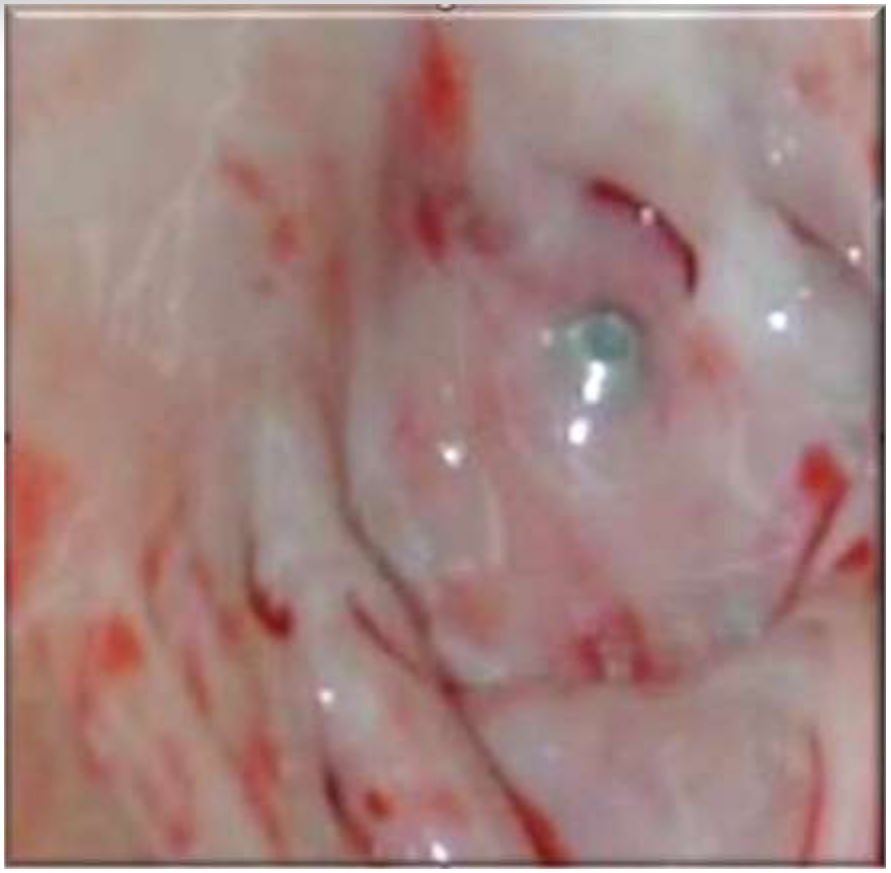


Canine Model – 30 Day



Canine Model – 45 Day



Human Pathology – 9 Months Post-implant
(Non-device related death)

Images on file at Boston Scientific Corporation.
Results in animal models may not necessarily be indicative of clinical outcomes.

WATCHMAN™ Clinical Leadership

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- The WATCHMAN™ LAAC Device is the **most studied LAAC device** and the **only one proven with long-term data** from randomized trials or multi-center registries
  - Five studies, >2400 patients, nearly 6000 patient-years of follow-up

- The WATCHMAN Device can be **implanted safely**[1], **enables patients to discontinue warfarin**[2] **and reduces AF stroke risk** comparably to warfarin[3].
  - 95% implant success rate[4]
  - >92% warfarin cessation after 45 days, >99% after 1 year[4]

- WATCHMAN™ therapy demonstrated comparable stroke risk reduction, and **statistically superior reductions in hemorrhagic stroke, disabling stroke and cardiovascular death** compared to warfarin over long-term follow-up[5,6]:
  - 32% in all cause stroke[6]
  - 85% in hemorrhagic stroke[5]
  - 63% in disabling stroke[6]
  - 56% in cardiovascular death[5]

1. PROTECT AF, CAP, PREVAIL and CAP2; 2. PROTECT AF, CAP, PREVAIL; 3. PROTECT AF; 4. Holmes, DR et al. JACC 2014; Vol. 64, No. 1; 5. Reddy, V et al. TCT 2014; 6. Reddy, V et al. JAMA 2014; Vol. 312, No. 19

Most Studied LAAC Device. Only One with Long-Term Clinical Data

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	PROTECT AF	CAP Registry	PREVAIL	CAP2 Registry	Totals
Enrollment	2005-2008	2008-2010	2010-2012	2012-2014	
Enrolled	800	566	461	579	**2406**
Randomized	707	---	407	---	**1114**
WATCHMAN: warfarin (2:1)	463 : 244	566	269 :138	579	1877: 382
Mean Follow-up (years)	4.0	3.7	2.2	0.58	N/A
Patient-years	2717	2022	860	332	**5931**

Source: FDA Oct 2014 Panel Sponsor Presentation.

Patient Risk Factors Across Trials

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Characteristic	PROTECT AF N=707	CAP N=566	PREVAIL N=407	CAP2 N=579	p-value
$CHADS_2$ Score	**2.2 ± 1.2**	**2.5 ± 1.2**	**2.6 ± 1.0**	**2.7 ± 1.1**	**<0.0001**
$CHADS_2$ Risk Factors (% of Patients)					
CHF	26.9	23.3	19.1	27.1	0.004
Hypertension	89.8	91.4	88.8	92.5	0.15
Age ≥ 75	43.1	53.6	51.8	59.7	<0.001
Diabetes	26.2	32.4	24.9	33.7	0.001
Stroke/TIA	18.5	27.8	30.4	29.0	<0.0001
CHA_2DS_2-VASc	**3.5 ± 1.6**	**3.9 ± 1.5**	**4.0 ± 1.2**	**4.5 ± 1.3**	**<0.0001**

Source: FDA Oct 2014 Panel Sponsor Presentation.

Implant Success & Warfarin Cessation

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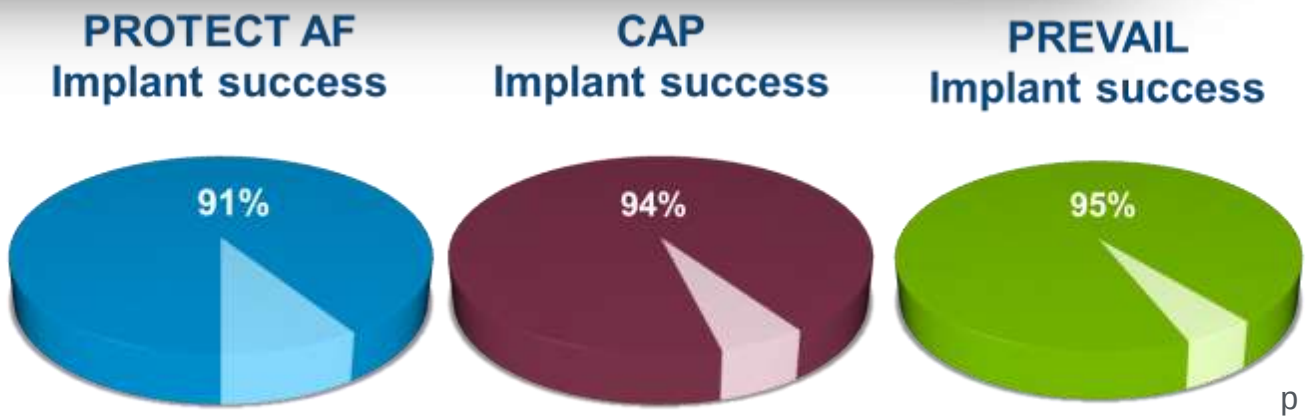

p = 0.04

Implant success defined as deployment and release of the device into the left atrial appendage

Warfarin Cessation

Study	45-day	12-month
PROTECT AF	87%	>93%
CAP	96%	>96%
PREVAIL	92%	>99%

PREVAIL Implant Success

No difference between new and experienced operators

Experienced Operators
- n=26
- 96%

New Operators
- n=24
- 93%

p = 0.28

PROTECT AF and CAP: Reddy, VY et al. Circulation. 2011;123:417-424.
PREVAIL: Holmes, DR et al. *JACC* 2014; 64(1):1-12.

WATCHMAN™ PROTECT AF Study Overview
Long-Term, Final 5-Year Results

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Study Design & Objective	Prospective, randomized (2:1), non-inferiority trial of LAA closure vs. warfarin in non-valvular AF patients for prevention of stroke
Primary Endpoint	Efficacy: Composite end point of stroke, cardiovascular death or systemic embolization Safety: Major bleeding, device embolization or pericardial effusion
Statistical Plan	All analyses by intention-to-treat Bayesian (stratified for $CHADS_2$ score) : Primary Efficacy and Safety endpoints Cox Proportional: All Secondary Analyses
Patient Population	n = 707 Mean $CHADS_2$= 2.2, CHA_2DS_2-VASc = 3.5
Key Inclusion Criteria	Paroxysmal / Persistent / Permanent AF CHADS ≥ 1 (93% had a CHA_2DS_2-VASc Score ≥2) Eligible for long-term warfarin therapy
Mean Follow-Up	2,717 patient-years, 48 months
Number of Sites	59 in the United States and Europe Enrollment Feb 2005 – June 2008

PROTECT AF: Final, 5-Year Primary Efficacy Events Consistent with 4-Year Results

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	Event Rate (per 100 Pt-Yrs)		Rate Ratio (95% CrI)	Posterior Probability	
	WATCHMAN	Warfarin		Non-inferiority	Superiority
Primary efficacy	**2.2**	**3.7**	**0.61** (0.42, 1.07)	**>99.9%**	**95.4%**
Stroke (all)	**1.5**	**2.2**	**0.68** (0.42, 1.37)	**99.9%**	**83%**
Systemic embolism	**0.2**	**0.0**	**N/A**	**--**	**--**
Death (CV/unexplained)	**1.0**	**2.3**	**0.44** (0.26, 0.90)	**>99.9%**	**98.9%**

Source: FDA Oct 2014 Panel Sponsor Presentation.

PROTECT AF 4-Year Results in JAMA

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JAMA®
The Journal of the American Medical Association

WATCHMAN™ Met Criteria for both Noninferiority and Superiority for the Primary Composite Endpoint Compared to Warfarin

Table 2. Intention-to-Treat Primary Efficacy and Safety Outcomes According to Treatment Group by Bayesian Model

Event	Device Group (n = 463)		Warfarin Group (n = 244)		Device/Warfarin Rate Ratio (95% Credible Interval)	Posterior Probabilities, %	
	Events/Patient-Years	Observed Rate[a]	Events/Patient-Years	Observed Rate[a]		Noninferiority	Superiority
Primary efficacy end point[b]	39/1720.2	2.3 (1.7-3.2)	34/900.8	3.8 (2.5-4.9)	0.60 (0.41-1.05)	>99	96
Stroke	26/1720.7	1.5 (1.0-2.2)	20/900.9	2.2 (1.3-3.1)	0.68 (0.42-1.37)	>99	83
Ischemic	24/1720.8	1.4 (0.9-2.1)	10/904.2	1.1 (0.5-1.7)	1.26 (0.72-3.28)	78	15
Hemorrhagic	3/1774.2	0.2 (0.0-0.4)	10/916.2	1.1 (0.5-1.8)	0.15 (0.03-0.49)	>99	99
Disabling[c]	8/1771.3	0.5 (0.2-0.8)	11/912.7	1.2 (0.6-1.9)	0.37 (0.15-1.00)	>99	98
Nondisabling[c]	18/1723.7	1.0 (0.7-1.7)	9/907.7	1.0 (0.4-1.7)	1.05 (0.54-2.80)	89	34
Systemic embolization	3/1773.6	0.2 (0.0-0.4)	0/919.5	0	NA		
Cardiovascular or unexplained death	17/1774.3	1.0 (0.6-1.5)	22/919.4	2.4 (1.4-3.4)	0.40 (0.23-0.82)	>99	99
Primary safety end point[d]	60/1666.2	3.6 (2.8-4.6)	27/878.2	3.1 (2.0-4.3)	1.17 (0.78-1.95)	98	20

Abbreviation: NA, not applicable.

[a] Events per 100 patient-years (95% credible interval).

[b] Primary efficacy defined as composite of stroke, systemic embolization, or cardiovascular/unexplained death.

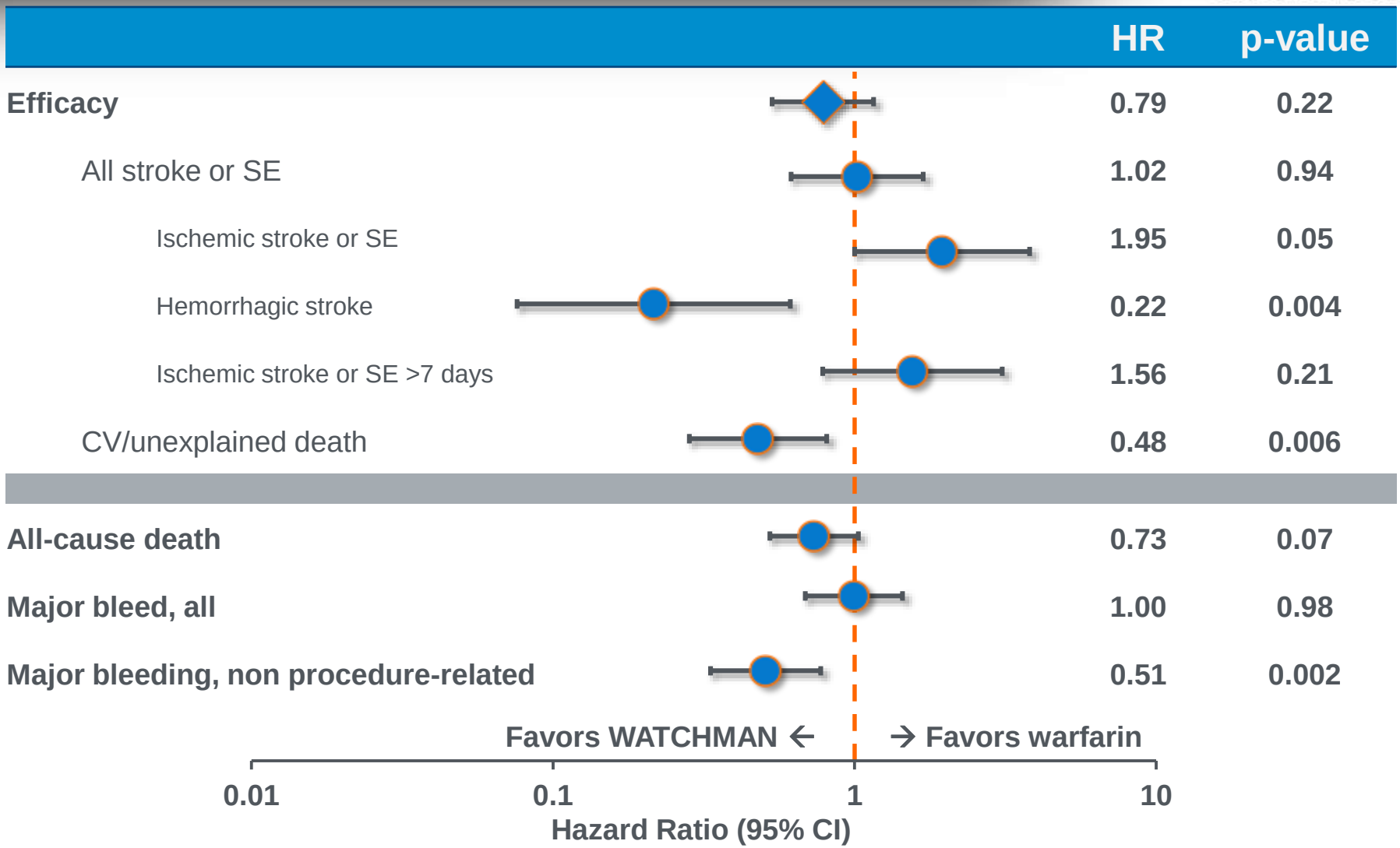
[c] Disabling or fatal strokes were those with a Modified Rankin Score of 3-6 after the stroke. Nondisabling strokes were those with Modified Rankin Scores of 0-2 after the stroke.

[d] Safety defined as procedure-related events (pericardial effusion requiring intervention or prolonged hospitalization, procedure-related stroke, or device embolization) and major bleeding (intracranial or bleeding requiring transfusion).

Reddy, VY et al. JAMA. 2014;312(19):1988-1998.

Meta-Analysis Shows Comparable Primary Efficacy Results to Warfarin

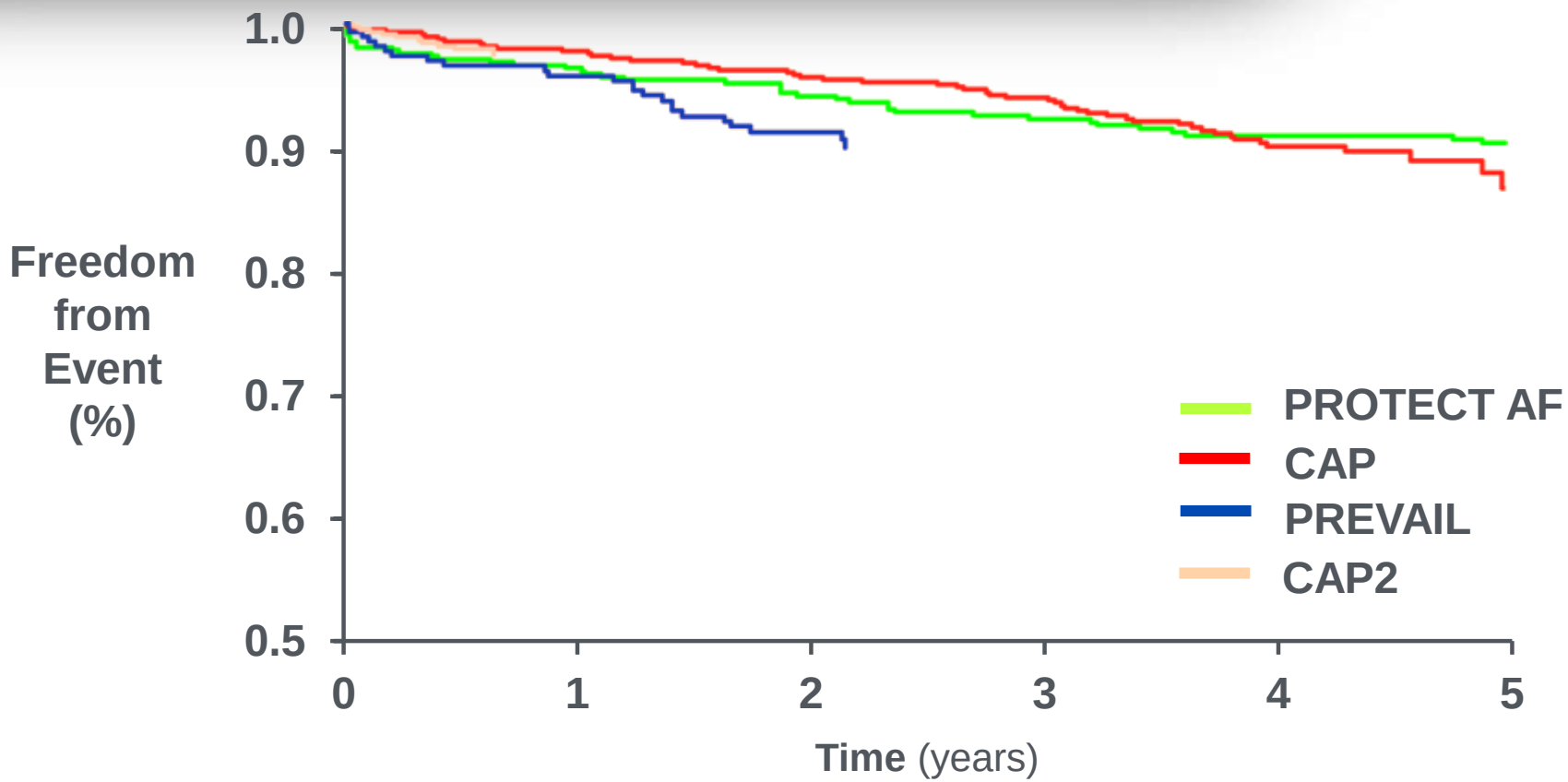
WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE



Source: Holmes DR, et al. Holmes, DR et al. *JACC* 2015; In Press. Combined data set of all PROTECT AF and PREVAIL WATCHMAN patients versus chronic warfarin patients

WATCHMAN Performance Consistent Across All 4 Data Sets

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

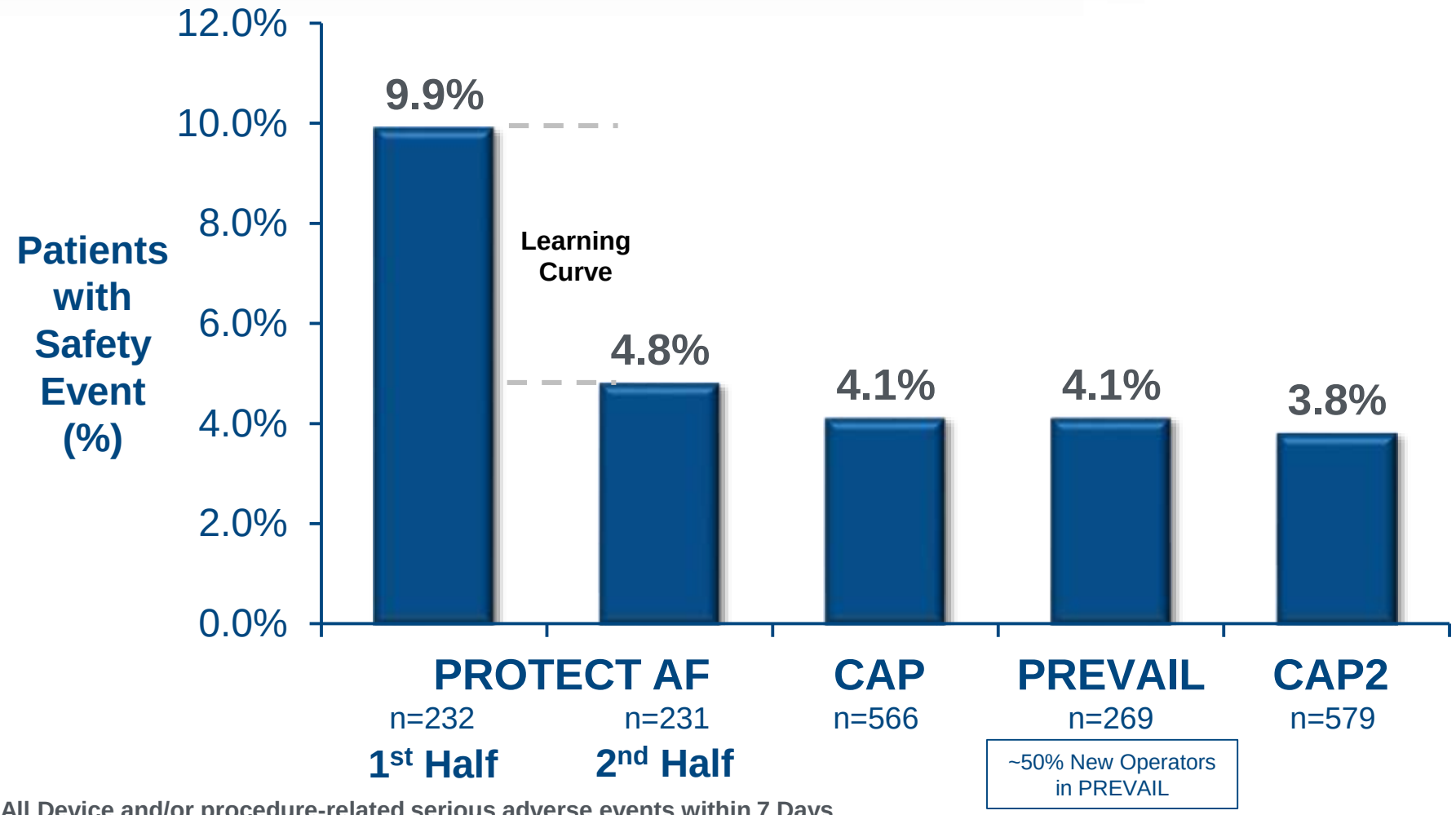


PROTECT AF	463	382	360	337	321	235
CAP	566	503	468	435	293	59
PREVAIL	269	234	182	37	0	
CAP2	579	116	0			

Source: Holmes DR, et al. Holmes, DR et al. *JACC* 2015; In Press. Combined data set of all PROTECT AF, CAP, PREVAIL and CAP 2 WATCHMAN patients

Favorable Procedural Safety Profile: 7-Day Safety Events

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE



All Device and/or procedure-related serious adverse events within 7 Days

Source: FDA Oct 2014 Panel Sponsor Presentation.

PROTECT AF/PREVAIL Pooled Analysis: Less Bleeding with WATCHMAN™ Device 6 Months Post-Implant

WATCHMAN™
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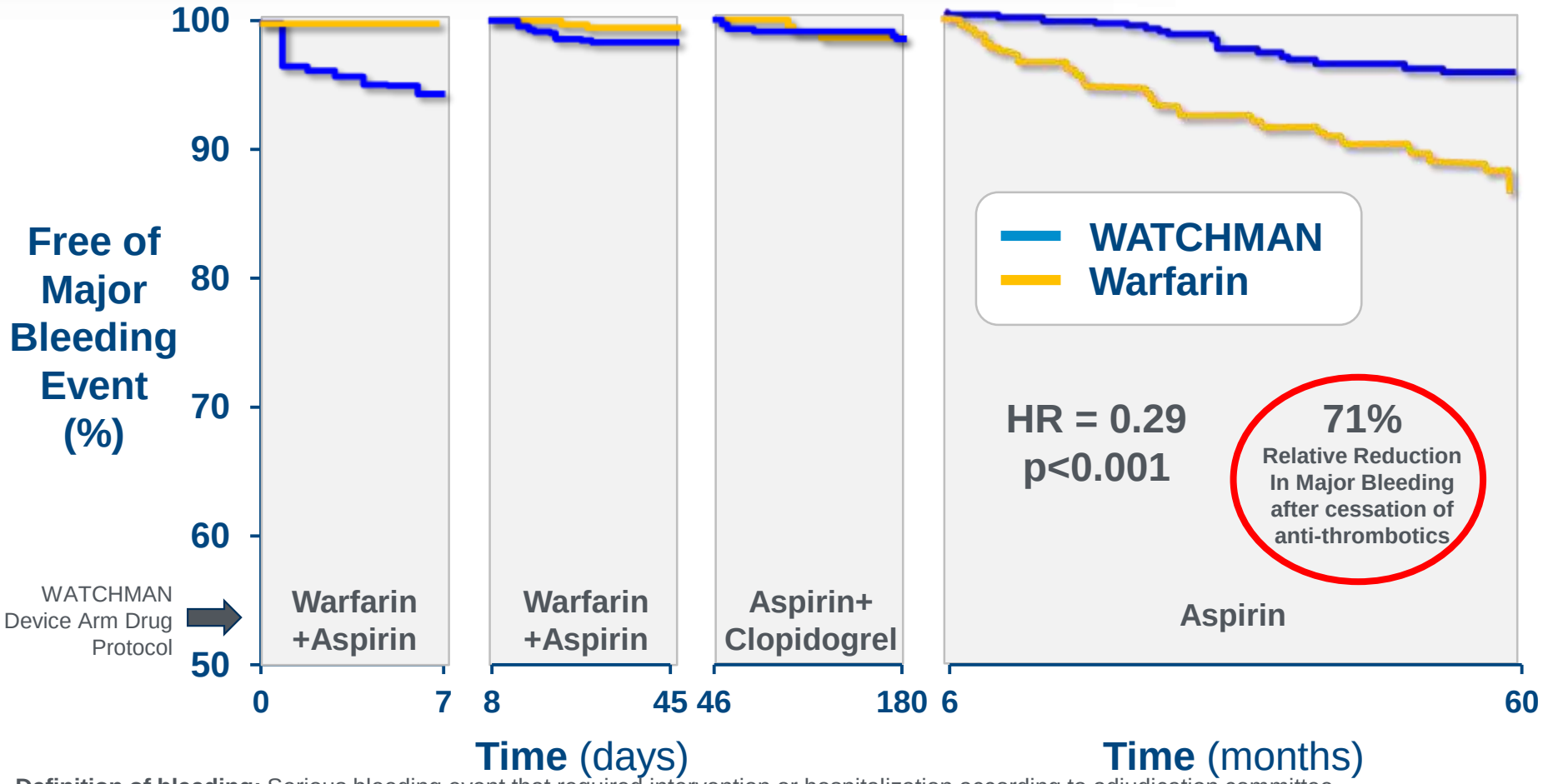
CLOSURE DEVICE

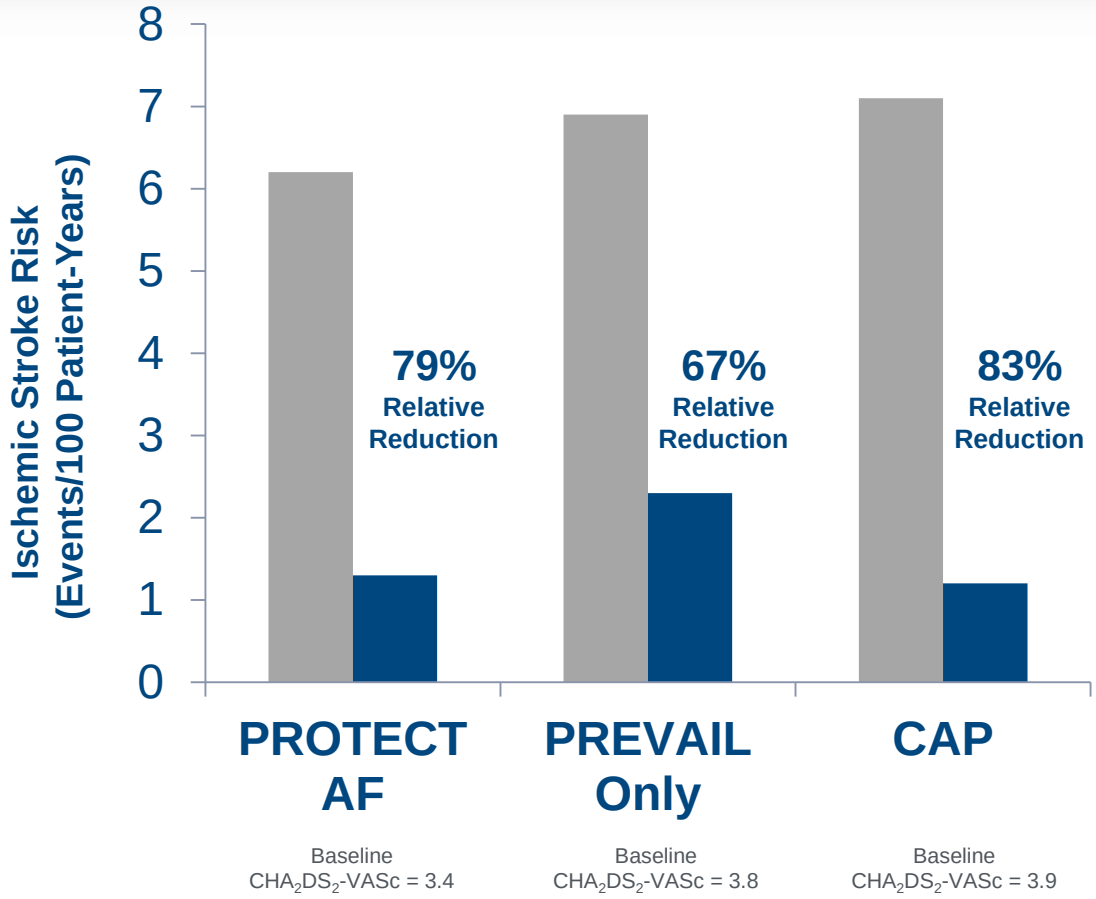


Definition of bleeding: Serious bleeding event that required intervention or hospitalization according to adjudication committee

Price, MJ. Avoidance of Major Bleeding with WATCHMAN Left Atrial Appendage Closure Compared with Long-Term Oral Anticoagulation : Pooled Analysis of the PROTECT-AF and PREVAIL RCTs. TCT 2014 (abstract)

WATCHMAN™ Device Reduces Ischemic Stroke Over No Therapy

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE



- Imputed Ischemic Stroke Rate*
- Observed WATCHMAN Ischemic Stroke Rate

* Imputation based on published rate with adjustment for CHA_2DS_2-VASc score (3.0); Olesen JB. Thromb Haemost (2011)

FDA Oct 2014 Panel Sponsor Presentation. Hanzel G, et al. TCT 2014 (abstract)

WATCHMAN Clinical Leadership

Continued Investment

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

- **EWOLUTION Registry**
  - Endpoints: Additional information in real-world setting
  - Est. Enrollment: Up to 1,000 patients
  - Target Follow-up Duration: 2 years
  - Sites: 75 international centers

- **WATCHMAN Asia Pacific (WASP) Registry**
  - Endpoints: Additional information in real-world setting
  - Est. Enrollment: 300 patients
  - Target Follow-up Duration: 2 years
  - Sites: 10 sites in Asia Pacific region

Questions?

WATCHMAN Approval and First Implants Underscore BSC Innovation

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

WATCHMAN LAAC Device FDA approval and first implant announcements have generated **44 million media impressions** with coverage that included **223 original broadcast segments and articles**

- **158 original print/online articles** resulting from FDA approval and first implant announcements
- **65 original TV and radio placements** resulting from FDA approval and first implant announcements
- **3.8 million impressions** resulting from 249 Satellite Media Tour (SMT) airings
- **3.4 million impressions** resulting from 872 Radio News Release (RNR) airings

MASS DEVICE

"Boston Scientific touts the 1st commercial implantations of its Watchman anti-stroke heart implant."

Bloomberg Business

"It recently won approval for Watchman, a device to close off a section of the heart where blood can pool to form deadly clots."

THE WALL STREET JOURNAL.

"The FDA approved Watchman as an alternative to a commonly-used blood thinner to prevent stroke in patients with an abnormal heartbeat known as atrial fibrillation."

WATCHMAN Physician Training

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Phase I **Self-Study and Expectation Setting**	**Online modules:** Procedure and case studies (with exam)
Phase II **Professional Training Event**	**Mandatory live 1-day Professional Training Event:** Taught by experienced WATCHMAN physician faculty • Optional 2nd day for live case viewing (2-3 cases)
Phase III **Initial Cases and Building Confidence through Cadence**	**First cases ideally completed w/i 2 weeks of PTE** Optional physician proctoring available for accounts who want it for first case day
Phase IV **Transition to Independence**	**Ongoing cases supported by WATCHMAN Clinical**

WATCHMAN™ Device Reimbursement Status

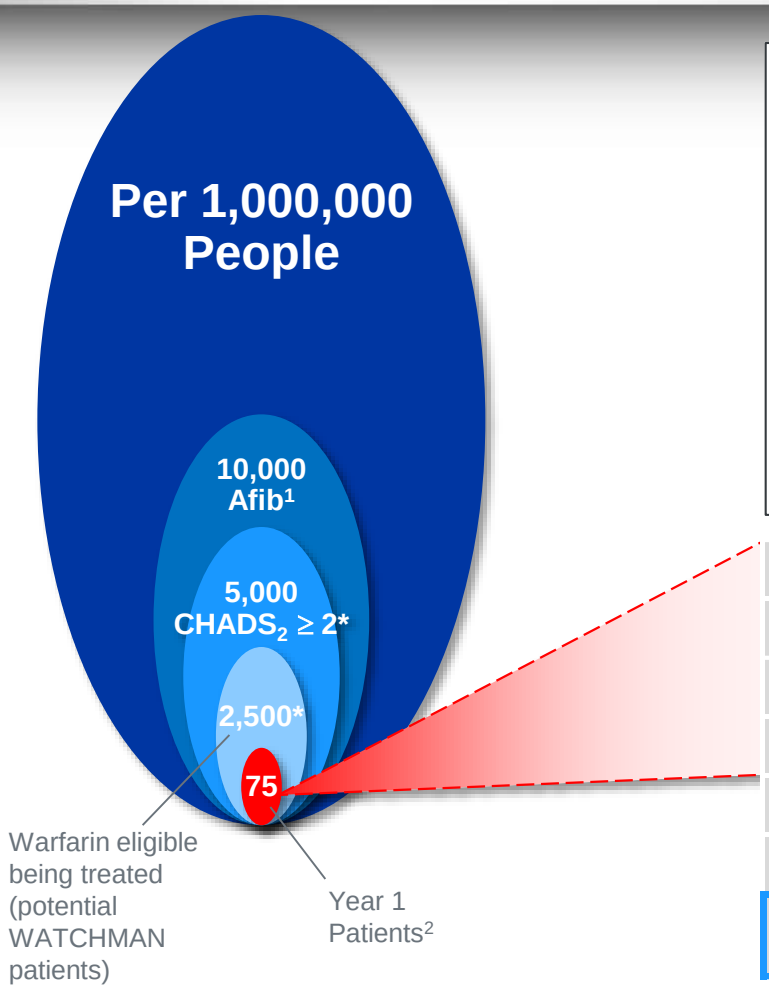
WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

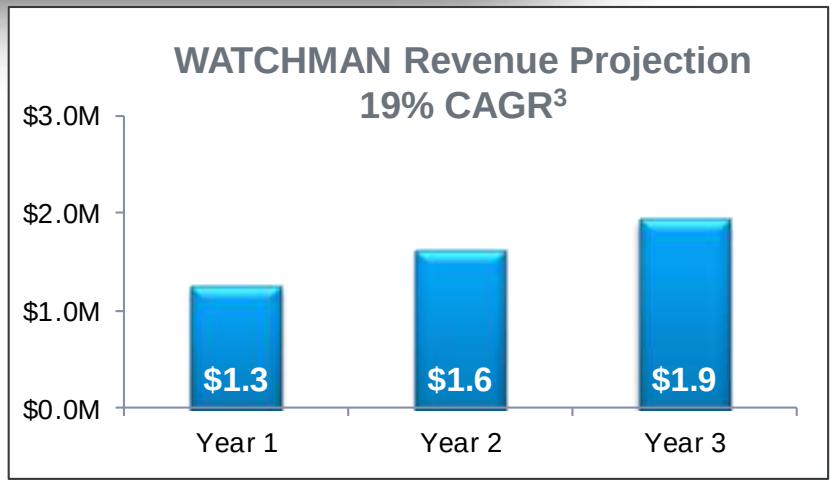
"Reimbursement" = Coding + Coverage + Payment Rates
Coding and Payment Rates established
Applied for National Coverage Determination after FDA approval

- Coverage gaps are routine for new novel technologies
- Proactively working with CMS to facilitate Medicare coverage now that FDA approval received
- In-Patient only procedure
- Anticipate a gap between FDA approval and coverage - it will be necessary for clinicians/hospitals to seek coverage on a case-by-case basis by appealing denials if they occur

Potential Impact of Adopting WATCHMAN™

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE





Year 1 Patients[2]	75
Average Reimbursement Implant[4]	$15,629
3 Follow-Up Visits[5]	$3,066
Year 1 (3.0% penetration)	$1.3M
Year 2 (3.5% penetration)[3]	$1.6M
Year 3 (4.0% penetration)[3]	$1.9M
3-Year Total	**$4.8M**

NOTE: This is an illustrative model. There is no guarantee of top line revenue growth and other variables may impact this model

[1] Figures from a variety of sources, all compiled in Lloyd-Jones D, Adams RJ, Brown TM, et al. Heart Disease and Stroke Statistics—2010 Update: a report from the American Heart Association. *Circulation*. 2010;121:e91. * Boston Scientific Estimates: 50% of AFib patients have CHADS$_2$ scores of 2 or more; 50% of Warfarin-eligible are being effectively treated. [2] Model 3% of patients in year 1, 3.5% in year 2, 4% in year 3. [3] 15% CAGR due to modeled increased penetration, plus 3.8% CAGR in AFib prevalence per Lloyd-Jones, Adams, Brown, et al. [4] 2013 national weighted average of DRG 250 & 251 at target WATCHMAN sites. [5] 2014 national average TEE payment

ABBREVIATED STATEMENT
WATCHMAN™ Left Atrial Appendage Closure Device with Delivery System and WATCHMAN Access System

Boston Scientific

INDICATIONS FOR USE

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for warfarin; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

The WATCHMAN Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.

CONTRAINDICATIONS

Do not use the WATCHMAN Device if:

- Intracardiac thrombus is visualized by echocardiographic imaging.
- An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a device. See **Table 46** in the DFU.
- Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
- There are contraindications to the use of warfarin, aspirin, or clopidogrel.
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device is contraindicated.

WARNINGS

- Device selection should be based on accurate LAA measurements obtained using fluoro and ultrasound guidance (TEE recommended) in multiple angles (e.g., 0º, 45º, 90º, 135º).
- Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria.
- If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE.
- The potential for device embolization exists with cardioversion <30 days following device implantation. Verify device position post-cardioversion during this period.
- Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.
- For single use only. Do not reuse, reprocess, or resterilize.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.
- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying the device.
- Use caution when introducing the WATCHMAN Access System to prevent damage to cardiac structures.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- To prevent damage to the Delivery Catheter or device, do not allow the WATCHMAN Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath.
- If using a power injector, the maximum pressure **should not** exceed 100 psi.
- In view of the concerns that were raised by the RE-ALIGN[1] study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to:

Air embolism, Airway trauma, Allergic reaction to contrast media/medications or device materials, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect , AV fistula , Bruising, hematoma or seroma, Cardiac perforation , Chest pain/discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cranial bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, Groin pain, Groin puncture bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection / pneumonia, Interatrial septum thrombus, Intratracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device / improper seal of the appendage / movement of device from appendage wall, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic , Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions

There may be other potential adverse events that are unforeseen at this time.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

[1]Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14.